K133364

JUL 2 2 2014

Attachment 5
510(K) Summary
PicoSure™ workstation

This 510(K) Summary of safety and effectiveness for the PicoSure™ workstation is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cynosure, Inc.
Address:	5 Carlisle Road Westford, MA 01886 USA
Contact Person:	Connie Hoy, VP of Regulatory Affairs
Telephone: Email:	1-781-993-2414 choy@cynosure, com
Preparation Date:	October 28, 2013
Device Trade Name:	PicoSure™ workstation
Common Name:	Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-4810
Legally Marketed Predicate Device(s):	PicoSure™ workstation (K)121346 Hoya ConBio RevLite (K)103118
Description of the PicoSure™ Workstation:	The PicoSure™ workstation is a high-powered Alexandrite system that delivers laser energy in the 755-nm wavelength. The system consists of a console that houses the power supply, control electronics and the laser. Laser energy is delivered to the skin via an articulated arm. The laser is activated using a footswitch.
Intended use of the PicoSure™ Workstation	The PicoSure™ workstation is indicated for tattoo and benign pigmented lesion removal. The PicoSure™ workstation operating with the 3mm or 6mm handpiece and the FOCUS lens array is indicated for the treatment of acne scars in Fitzpatrick skin types I-IV.
Performance Data:	IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance Steam Sterilization Test Report 673257 Software Verification and Validation Testing Report 860-7012-SRV

Results of Clinical Study:

Two clinical studies were conducted.

One study assessed facial acne scars. In 17 patients who completed the study, a total of 46 acne scars underwent a mean of 6.3 treatments with either the 3mm or 6mm handpiece, each operated with the FOCUS lens array. Before and after photographs were evaluated by three blinded evaluators, who were able to identify correctly the before and after images in 70% of the 17 subjects. The mean improvement score (scale 0-3) was 1.9. The non-blinded treating physician reported a 100% overall satisfaction rate, scoring the improvement in 47% of subjects as "satisfied" and 53% as "extremely satisfied." Subjects reported a satisfaction rate of 87% (53% "satisfied" and 27% "extremely satisfied").

A second study was conducted on normal skin on the arm of 2 subjects and the leg of the 3rd subject. to evaluate the tissue response to treatment with the FOCUS lens array. Three patients were treated with the 6mm lens with FOCUS array at 0.71J/cm^2 and with the 3mm lens with FOCUS array at 2.83J/cm^{2}Biopsies were performed in untreated skin and in treated skin immediately post treatment, 7 days post treatment, and 15 days post treatment. Treatment induced immediate focal epidermal vacuolization and small foci of degenerated keratinocytes. At days 7 and 15, skin exhibited intact epidermis with mild, superficial dermal lymphocytic infiltrates in a peri-vascular pattern.

Technical Specifications Comparison:

	PicoSure™ Workstation (current submission)	PicoSure™ Workstation (previously cleared)	RevLite
Laser Type	Alexandrite	Alexandrite	Nd:YAG
Wavelength	755nm	755nm	532 nm, 585 nm 650 nm, & 1064 nm
Energy per pulse	0.2 J/cm2	0.2 J/cm2	0.85 J/cm2
Maximum Average Fluence	6.37 J/cm^2	6.37 J/cm^2	12 J/ cm^2 (1064nm) 5 J/ cm^2 (532nm) 10 J/ cm^2 (585nm) 6 J/ cm^2 (650 nm) 1.2 J/ cm^2 (532Lite)
Repetition Rate	Single pulse, or 1, 2.5, 5, or 10 pulse(s) per second (Hz)	Single pulse, or 1,2,5, or 10 pulse(s) per second (Hz)	Single & double pulse, 1, 2, 5, & 10 Hz pulses per second
Pulse Width	≤ 0.9 ns	≤ 0.9 ns	5-20 ns
Spot Sizes	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm With FOCUS lens array: 3mm, 6mm	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm	Fixed 2 – 8 mm (varies by wavelength)

Conclusion:

The PicoSure Workstation is substantially equivalent to other existing laser systems in commercial distribution for use in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2014

Cynosure Incorporated
Ms. Connie Hoy
Vice President of Regulatory Affairs
5 Carlisle Road
Westford, Massachusetts 01886

Re: K133364
Trade/Device Name: PicoSure workstation
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 15, 2014
Received: June 17, 2014

Dear Ms. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133364

Device Name
PicoSure workstation

Indications for Use *(Describe)*
The PicoSure workstation is indicated for tattoo and benign pigmented lesion removal and for the treatment of Acne Scars in skin Types I-IV.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.07.21 11:17:25 -04'00' For BSA

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